510(K) SUMMARY

ARTHROCARE CORPORATION

OPUS SMARTSTITCH SUTURE DEVICE WITH S-CONNECTOR

OCT - 2 2006

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-3523
Establishment Registration No.:	2951580
Contact Person:	Laura N. Kasperowicz Sr. Manager, Regulatory Affairs
Date Prepared:	July 28, 2006

Device Description

Trade Name:	Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector
Generic/Common Name:	Endoscopic suture device
Classification Name:	Endoscope and accessories (Class II per 21 CFR 876.1500)
Product Code:	KOG

Predicate Device

Opus SmartStitch Suture Device	K030170 (Cleared 07/28/03)

Product Description

The Opus® SmartStitch™Suture Device with PerfectPasser™ Connector is designed to allow the surgeon the option to place a simple stitch or a mattress stitch.

Indications For Use

The Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector is indicated for use for placement of braided polyester or polyethylene suture through soft tissue in endoscopic and other limited access procedures.

510(K) SUMMARY

Substantial Equivalence

By definition, substantial equivalence means that a device has the same intended use and technical characteristics as the predicate device, or has the same intended use and different technological characteristics, but can be demonstrated to be as safe and effective as the predicate device. The Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector is substantially equivalent to the existing Opus® SmartStitch™ Suture Device with M-Connector cleared by the Food & Drug Administration (K030170). The differences between the Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector and the predicate device does not raise any questions regarding the safety and effectiveness. Furthermore, the materials are well characterized and have been used in the predicate device with the same indications. The device, as designed, is as safe and effective as the predicate device.

Summary and Reason for 510(k) Notification

The purpose of this 510(k) is to notify the Food and Drug Administration of a modification to the previously cleared device. The modification incorporates the same principal of operation and fundamental technology as the previously cleared Opus SmartStitch Suture Device with M-Connector. The primary difference is a modification to the suture delivery system, which will allow the surgeon the option to place a simple stitch or a mattress stitch. The proposed PerfectPasser™ Connector design incorporates dimensional modifications that allow increased tissue margin during placement of the stitch. The S-Connector design includes the use of the following alternative materials: glass-filled polycarbonate and a glass-filled nylon. The predicate device, the M-Connector, was originally cleared for use with a braided polyester suture. The PerfectPasser™ Connector has been designed to use either braided polyester suture or braided polyethylene suture. The product labeling has been changed to incorporate the new product name and alternative suture material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2006

ArthroCare Corporation
% Ms. Laura N. Kasperowicz
Sr. Manager. Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale. California 94085-3523

Re: K062244
Trade/Device Name: Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: KOG
Dated: August 30. 2006
Received: September 13. 2006

Dear Ms. Kasperowicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28. 1976. the enactment date of the Medical Device Amendments. or to devices that have been reclassified in accordance with the provisions of the Federal Food. Drug. and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may. therefore. market the device. subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration. listing of devices. good manufacturing practice. labeling. and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA). it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations. Title 21. Parts 800 to 898. In addition. FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements. including. but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable. the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K 062244

Device Name: Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector

Indications for Use:

The Opus® SmartStitch™ Suture Device with PerfectPasser™ Connector is indicated for use for placement of braided polyester and polyethylene suture through soft tissue in endoscopic and other limited access procedures.

Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	NO

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062244